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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,955	07/19/2001	Anil K. Saksena	IN01159K	4478

24265 7590 09/30/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
MONDESI, ROBERT B	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/30/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/908,955	Applicant(s) SAKSENA ET AL.	
	Examiner Robert B Mondesi	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *35-38,44-49 and 65* is/are withdrawn from consideration.

5)☒ Claim(s) *61 and 62* is/are allowed.

6)☒ Claim(s) *1,2,30,33,39-40,42,51-60 and 63* is/are rejected.

7)☒ Claim(s) *3-29,31,32,34,41,43,50 and 64* is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-34, 39-43, 50-64 drawn to peptides and pharmaceutical compositions, classified in Class 514 subclass 17.

II. Claims 35-38, 44-49 and 65, drawn to process of use or method of treatment of Hepatitis C, classified in Class 424, subclass 9.1.

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case: product can be used in the alternative processes of apoptosis of cells.

3. This application contains claims directed to the following patentably distinct compounds of the claimed invention: In claims, 1-34 the presence of a compound general structure formula (Formula 1) and the ability to substitute a variety of independently selected moieties in positions A, E, G, J, L, M, Q, W, Y, Z, R1, R2, R3 and R4 has given rise to a multitude of compounds. Each one of these compounds is patentably distinct absent factual evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect a single disclosed moiety in positions A, E, G, J, L, M, Q, W, Y, Z, R1, R2, R3 and R4 that is searchable for

prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the moieties selected in positions A, E, G, J, L, M, Q, W, Y, Z, R1, R2, R3 and R4 in the general formula (Formula I) are set forth in a series of alternatives.

Applicant is advised that a reply to this requirement must include a single moiety in positions A, E, G, J, L, M, Q, W, Y, Z, R1, R2, R3, and R4 that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the peptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the peptides to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. This application contains claims directed to the following patentably distinct compounds of the claimed invention: In claims 39-43 a multitude of compounds are presented. Each one of these compounds exhibits different biological properties, for example some of the compounds can be proton donors involved in acid base reactions and some of the other compounds can participate more readily in a SN1 type reaction. Each one of these compounds is patentably distinct absent factual evidence to the contrary.

Applicant is required under 35 U.S.C. 121 to elect a single compound from the group of compounds presented in claims 1-34, 39-43, and 50-64.

Applicant is advised that a reply to this requirement must include a single compound from the list of compounds that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the peptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the peptides to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

During a telephone conversation with Mr. Harvey Cohen on 09-10-03 a provisional election was made with traverse to prosecute the invention of Group

I, claims 1-34, 39-43, 50-64 with a further election of a compound core structure represented by compound in claim 53. Affirmation of this election must be made by applicant in replying to this Office action. Claim 35-38, 44-49 and 65 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

The applicant has not claimed priority to an earlier application.

Preliminary Amendment

The preliminary amendment filed 10/01/2001 has been entered. New claims 51-65 have been added. The pending claims are 1-65.

Information Disclosure Statement

The IDSs filed 01/02/2002 and 07/18/2002 have been received, entered and considered. A signed copy of PTO-1449 for these IDSs is attached.

Claim Objections

Claims 3-29, 31-32, 34, 41, 43 and 64 are objected to because they depend from a rejected base claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 33, 39-40, 42, 51-60 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 provides for the use of a pharmaceutical composition and a compound, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

In **claim 33 and 63** the phrase "still additionally" is indefinite.

In **claims 30, 39-40 and 51-60** "HCV" needs to be spelled out in the first instance of use..

In **claim 42 and 63** "PEG" needs to be spelled out in the first instance of use.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

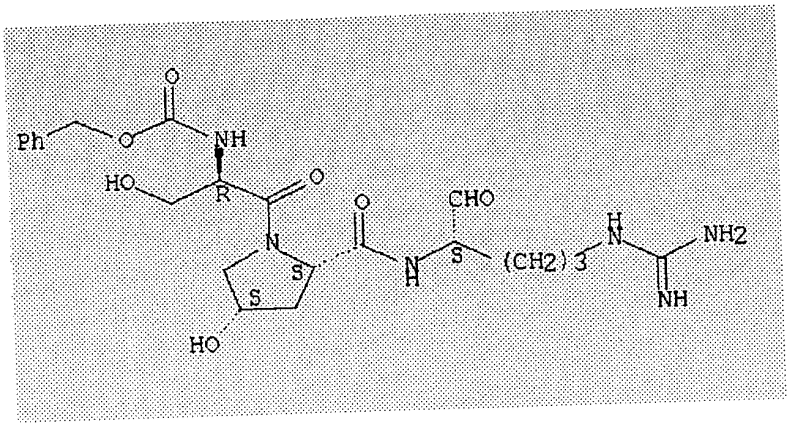
Claim 30 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Insofar as this is a composition claim, the process recited does not per se modify the composition and therefore has no applicable patentable weight.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Brunk et al. WO 00/05245. Brunk et al. teach, (pages 33, line 12, to page 43 line 7, and claim 1, pages 159-167), the following structure;



Claim 1 recites a structure according to the compound Formula I, with the following limitations; J may be (CH_2), G may be (CH_2), L may be CH, E may be CH, Q and M may be absent and when Q and M are absent A is directly linked to L, A may be O, R_1 may be COR_5 and R_5 may be OH, R_2 may be an amino, R_3 may be an C_1-C_{10} alkyl where said alkyl is optionally substituted with a hydroxy, Z may be N, R_4 maybe H, W may be C=O and Y may be an alkoxy. **Claim 2** is a further limitation of **claim 1** that states R_1 may be COR_5 and R_5 may be OH. Thus Brunk et al. teach all the elements of **claims 1 and 2** and these claims are anticipated under 35 USC 102(b).

Conclusion

Claims 61 and 62 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 703-305-4445. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The

fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Robert B Mondesi
Patent Examiner
09-28-03

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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